The Finecare™ NT-proBNP Rapid Quantitative Test is a fluorescence immunnoassay for quantitative measurement of N-terminal prohormone of brain natriuretic peptide (NT-proBNP) in human whole blood, serum or plasma.

PRINCIPLE

The Finecare™ NT-proBNP Rapid Quantitative Test is based on fluorescence immunoassay technology. The Finecare™ NT-proBNP Rapid Quantitative Test uses a sandwich immunodetection method, when sample is added to the sample well of the test, the fluorescent-labeled detector-anti-NT-proBNP antibody binds to NT-proBNP antigen in blood specimen. As the sample mixture migrates on the microfluidic paper-based matrix of test strip by capillary action, the complexes of detector antibody and NT-proBNP are captured to anti-NT-proBNP antibody that has been immobilized on test strip. Thus the more NT-proBNP antigen is in blood specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of NT-proBNP captured and Finecare™ FIA Meter shows NT-proBNP concentrations in blood specimen. The within-run precision of Finecare™ NT-proBNP Rapid Quantitative Test is displayed as XXX pg/mL from Finecare™ FIA Meter. The working range and the detection limit of the NT-proBNP Test system are 18-35000 pg/mL and 18 pg/mL.

PRECAUTIONS

1. This kit is for in vitro diagnostic use only. Do not swallow.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Don't use Test Cartridge if its lot # does not match with ID Chip # that is inserted and clinic at which the sample(s) is taken by qualified medical personnel.
5. Place the kit in the dark or under subdued lighting. Do not light up or expose to direct sunlight.
6. Discard after single use.

MATERIAL

<table>
<thead>
<tr>
<th>Material Provided</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finecare™ FIA Meter</td>
<td>1</td>
</tr>
<tr>
<td>Test Cartridge</td>
<td>25</td>
</tr>
<tr>
<td>Test Cartridge ID Chip</td>
<td>1</td>
</tr>
<tr>
<td>Detector buffer</td>
<td>25</td>
</tr>
<tr>
<td>Leaflet of instruction</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Material Required But Not Provided</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finecare™ FIA Meter</td>
</tr>
<tr>
<td>Transfer Pipette Set (100uL size)</td>
</tr>
<tr>
<td>Specimen Collection Containers</td>
</tr>
<tr>
<td>Air Drying Pad</td>
</tr>
<tr>
<td>Cartridge (for Plasma/Serum only)</td>
</tr>
<tr>
<td>Timer</td>
</tr>
</tbody>
</table>

STORAGE AND STABILITY

1. Store the detector buffer at 4 – 30 ºC. The buffer is stable up to 24 months.
2. Store Finecare™ NT-proBNP Rapid Quantitative Test Cartridge at -30 ºC, shelf life is up to 24 months.

3. Test cartridge should be used within 1 hour after opening the pack.

TEST PROCEDURE

Refer to Finecare™ FIA Meter Operation Manual for the complete instructions on use of the Test. The test should be performed in room temperature.

Step 1: Preparation

Before testing, activate “use” in setting then save it.

Check/insert ID Chip into the equipment.

Step 2: Sampling

Mix well the specimen with buffer for 1 minute by tapping or inverting the tube.

Step 3: Loading
nonresponsiveness of antigen to the antibodies by that certain unknown components are masking its epitope, such that antigen cannot be seen by the antibodies; instability of NT-proBNP antigen, resulting in degradation with time and temperature, such that it becomes no longer recognizable by antibodies; and degraded other test components. The effectiveness of the test is highly dependent on storage of kits and sample specimens at optimal conditions.

4. Plasma using anticoagulants (e.g. heparin or citrate) other than EDTA has not been evaluated in Finecare™ NT-proBNP Rapid Quantitative Test and thus should not be used.

5. Other factors may interfere with Finecare™ NT-proBNP Rapid Quantitative Test and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparison study using 211 human blood samples, demonstrated good correlation with a commercially available kit. Comparison between the Finecare™ NT-proBNP Rapid Quantitative Test and the Roche Diagnostics GmbH NT-proBNP STAT for the 211 clinical samples, the Correlation Coefficient is 0.974.

Assay Range and Detection Limit:

- Assay Range: 18 - 35000 pg/mL
- Detection Limit: 18 pg/mL

Linearity

A serial concentration of NT-proBNP controls at 120 pg/mL, 450 pg/mL, 1500 pg/mL, 3000 pg/mL, 6000 pg/mL, 15000 pg/mL were each tested for three times, the Correlation Coefficient (R) is ≥0.995.

BIBLIOGRAPHY OF SUGGESTED READING


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4. Do not mix components from different kit lots.

5. The Finecare™ NT-proBNP Rapid Quantitative Test kit is only operational in

6. Timer

7. The Test Cartridge and Meter should be used away from vibration and

8. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.

9. Collection of sample:

A. Blood collection:

- Specimen Collection Containers

B. Serum/Plasma:

- Blood collection tube containing suitable anticoagulant (EDTA recommended).

Step 2: Sampling

1. BHIBIBLIOGRAPHY OF SUGGESTED READING


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